IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CIPLA USA, INC.	)	
	)	
Plaintiff,	)	
	)	C.A. No.:
v.	)	
	)	
IPSEN BIOPHARMACEUTICALS, INC.	)	**DEMAND FOR JURY TRIAL**
	)	
Defendant.	)	

COMPLAINT

Plaintiff Cipla USA, Inc. ("Cipla"), through counsel, brings this action against Defendant Ipsen Biopharmaceuticals, Inc. ("Ipsen") and alleges as follows:

NATURE OF THE ACTION

1. This case arises from the unlawful efforts of Defendant Ipsen to stifle long-awaited competition against its most valuable product. Ipsen is a biopharmaceutical drug company that manufactures medical products, including Somatuline® Depot—a drug injection with the active ingredient Lanreotide Acetate (a synthetic hormone). Somatuline® Depot is used to treat certain rare diseases by slowing the growth of tumors. Ipsen began marketing Somatuline® Depot in August 2007, and it enjoyed more than 15 years of an effective monopoly as the only Lanreotide Acetate injection product approved by the U.S. Food and Drug Administration ("FDA"). That *de facto* exclusivity has been extremely lucrative for Ipsen: in the 12-month period ending in October 2021, Ipsen recorded around $867 million in U.S. sales. *See* Bhaskar Dutta, *Cipla gains 3% on USFDA nod to market Lanreotide*, The Economic Times (Dec. 20, 2021), https://bit.ly/3KOUGe2.

2. On December 17, 2021, the FDA approved the application of InvaGen Pharmaceuticals, Inc., an affiliate of Cipla, to market a Lanreotide Acetate injection product ("Cipla's Lanreotide Acetate Product"). Cipla's Lanreotide Acetate Product was approved under

what is commonly referred to as the FDA's "Section 505(b)(2) pathway" for New Drug Approvals, *see* 21 U.S.C. § 355(b)(2). Under that pathway, InvaGen had to prove to the FDA that its product is safe and effective for its intended use, which the company did in part by referencing studies that established the safety and efficacy of Somatuline® Depot. InvaGen licenses Cipla's Lanreotide Acetate Product for distribution by Cipla.

3. The active ingredient, route of administration, indication,[1] dosages, and strengths of Cipla's Lanreotide Acetate Product are the same as Somatuline® Depot. Cipla has submitted a petition to the FDA requesting that the agency designate Cipla's Lanreotide Acetate Product as therapeutically equivalent to Somatuline® Depot. That request is currently pending.

4. On the first business day after Cipla announced that it had obtained FDA approval for Cipla's Lanreotide Acetate Product, Ipsen's stock price dropped by over 7% and financial analysts predicted that U.S. sales of Somatuline® Depot would decrease by 20% in FY 2022. *See* Elena Vardon & Anait Miridzhanian, *BUZZ-Ipsen drops after FDA approves competitor's generic drug*, Reuters News (Dec. 20, 2021), https://bit.ly/37sw8sT.

5. Faced with an impending loss of sales for its blockbuster product, Ipsen has resorted to subterfuge rather than engage in legitimate competition on the merits. Ipsen has repeatedly made false and/or misleading statements about Cipla and Cipla's Lanreotide Acetate Product to Cipla's customers and providers (clinics), which has undermined customers' confidence in Cipla, Cipla's Lanreotide Acetate Product, and the insurance coverage for Cipla's Lanreotide Acetate Product. Examples of Ipsen's false and/or misleading statements to Cipla customers include:

a. Ipsen stated that Cipla misrepresented the approval status of its Lanreotide Acetate Product by claiming that it is therapeutically equivalent to Somatuline® Depot. That statement is

[1] Cipla's Lanreotide Acetate Product shares two of Somatuline® Depot's three indications: acromegaly and gastroenteropancreatic neuroendocrine tumors.

literally false because Cipla never made any such claim. Rather, Cipla announced (accurately) that "[t]he active ingredient, route of administration and strengths" of its Lanreotide Acetate Product "are the same as SOMATULINE DEPOT®." *Cipla Receives Final Approval for Lanreotide Injection*, Cipla (Dec. 19, 2021), https://bit.ly/3vjRnGw. Cipla has repeatedly told Ipsen that Cipla never claimed the products are therapeutically equivalent, yet Ipsen has persisted in making this untrue accusation.

b. Ipsen stated that Somatuline® Depot and Cipla's Lanreotide Acetate Product must have independent Level II codes under the Healthcare Common Procedure Coding System ("HCPCS"), and that Cipla's product cannot use the existing code for the non-proprietary product name "Lanreotide 1 mg." This statement is false and/or misleading because neither Ipsen nor Cipla determines the appropriate billing code for a medical treatment. Rather, the Centers for Medicare and Medicaid Services ("CMS") has exclusive authority to assign HCPCS codes. CMS has not yet determined the appropriate HCPCS code for Cipla's Lanreotide Acetate Product, so Ipsen's unilateral assertion that Cipla's product is not eligible to use the existing J-code for "Lanreotide 1 mg" is wrong.

c. Ipsen stated that J3490 (the code for miscellaneous drugs) "must be used" for Cipla's Lanreotide Acetate Product until CMS assigns a unique code for the product. This statement is false and/or misleading, as it wrongly assumes the outcome of an agency process that remains ongoing. In guidance, CMS explains that it retains the flexibility to assign newly approved products like Cipla's Lanreotide Acetate Product to a unique code, to assign such a product to an existing code, or to determine that the code for miscellaneous drugs should be used. *See 5/18/07 – Update to Information Regarding Medicare Payment and Coding for Drugs and Biologics*, at 1, Ctrs. for Medicare and Medicaid Servs., https://go.cms.gov/3xyrLXZ.

d. Ipsen stated that use of J1930 (the HCPCS code currently assigned to Somatuline® Depot) for Cipla's Lanreotide Acetate Product "may lead to payment delays, reversals, and denials." This statement wrongly implies that use of the J1930 code for Cipla's Lanreotide Acetate Product is improper, which is false and/or misleading for the reasons stated above. The statement is misleading for the additional reason that it wrongly implies that Cipla's Lanreotide Acetate Product is not covered by Medicare or by private, commercial insurance. To the contrary, Cipla's Lanreotide Acetate Product is a physician administered injectable furnished "incident to" physician's services. As such, Cipla's Lanreotide Acetate Product is covered by Medicare Part B. Assignment of an HCPCS code is not a prerequisite to Medicare Part B coverage. Furthermore, because private, commercial insurers also use HCPCS codes to facilitate billing, Ipsen's statement suggests that such insurers may delay, reverse, or deny claims for Cipla's Lanreotide Acetate Product if billed under J1930. That is wrong. Cipla's Lanreotide Acetate Product would be covered by a private, commercial insurance if the drug is covered under the health plan's policy irrespective of any question regarding the HCPCS code. Ipsen's contrary insinuation falsely maligned Cipla's Lanreotide Acetate Product and damaged Cipla by leading providers both under the Medicare system and commercial insurance to suspect that reimbursements of Cipla's Lanreotide Acetate Product would lead to the reversal of existing reimbursements and the impairment of future reimbursement.

e. Ipsen stated that Cipla's Lanreotide Acetate Product is not reimbursable under HCPCS billing and payment code J1930. This is false and/or misleading. Ipsen's statement wrongly implies that CMS has made a determination that payment code J1930 cannot be used for Cipla's Lanreotide Acetate Product, which is false. Ipsen also wrongly implies that HCPCS codes affect coverage determinations by CMS and/or private insurers, which is not accurate.

6. Ipsen's false and/or misleading statements were intended to generate, and did generate, confusion surrounding whether and how purchases of Cipla's Lanreotide Acetate Product would be reimbursed by Medicare and commercial providers. Ipsen used its dominant position in the market to disparage Cipla and Cipla's Lanreotide Acetate Product in an effort to sway providers and wholesale distributors to purchase and subscribe Ipsen's product as opposed to Cipla's product, to unlawfully preserve its monopoly by shutting out the one competitor in the market by unfair means. The result has been to substantially depress demand for Cipla's Lanreotide Acetate Product, with Cipla's sales decreasing considerably after Ipsen began to disseminate its false and/or misleading statements.

7. Ipsen has caused Cipla to suffer substantial damages from the impairment of Cipla's business relationships, negative impact on Cipla's reputation, and lost goodwill. Ipsen has also caused Cipla to suffer damages from lost sales because customers (wholesale distributors and providers) purchased Somatuline® Depot instead of Cipla's Lanreotide Acetate Product—precisely as Ipsen intended.

8. Cipla brings this action to rectify the damage wrought by Ipsen's false and/or misleading statements and seeks both damages and permanent injunctive relief. As set forth below, Ipsen's conduct violates Section 43(a) of the Lanham Act (15 U.S.C. § 1125(a)), the Delaware Uniform Deceptive Trade Practices Act (6 *Del. C.* § 2531 *et seq.*), and Delaware common law prohibitions on unfair competition, tortious interference with economic advantage, and trade libel.

THE PARTIES

9. Upon information and belief, Ipsen is a Delaware corporation with a principal place of business at 1 Main Street, Suite 700, Cambridge, Massachusetts 02142.

10. Cipla is a Delaware corporation with a principal place of business at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059-2730.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 because Cipla's first claim arises under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and this Court has supplemental jurisdiction over Cipla's remaining state-law claims under 28 U.S.C. § 1367(a), because such claims are so related to the claim under Section 43(a) of the Lanham Act that they form part of the same case or controversy under Article III of the United States Constitution.

12. This Court has personal jurisdiction over Ipsen because Ipsen is incorporated in Delaware.

13. Venue is proper in the U.S. District Court for the District of Delaware pursuant to 28 U.S.C. § 1391 because Ipsen is a "resident" of Delaware, *see* 28 U.S.C. § 1391(b)(1), (c)(2).

BACKGROUND ON BILLING CODING AND COVERAGE

I. PROVIDERS USE HCPCS CODES TO IDENTIFY MEDICAL TREATMENTS IN ORDER TO FACILITATE EFFICIENT CLAIMS PROCESSING.

14. In the United States, health care insurers process over five billion claims for payment each year. *See Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures*, Ctrs. for Medicare & Medicaid Servs., https://go.cms.gov/3KT7dNL.

15. To ensure the orderly and consistent processing of health care claims, the Health Insurance Portability and Accountability Act ("HIPAA") requires the Secretary for Health and Human Services ("HHS") to adopt standards for coding systems that are used for reporting health care transactions.

16. Under the regulation promulgated to implement HIPAA's coding requirement (45 C.F.R. § 162.1002), HCPCS is the standardized coding system for describing and identifying health care equipment and supplies in health care transactions that are not within the jurisdiction of the Current Procedural Terminology ("CPT") code set.

17. HHS has delegated its exclusive authority under HIPAA to CMS to maintain and distribute HCPCS codes.

18. Thus, CMS is responsible for making decisions about additions, revisions, and deletions to the national alpha-numeric codes.

19. There is a CMS HCPCS Workgroup that reviews applications to change HCPCS codes (including by assigning codes to newly approved drugs) at regularly scheduled meetings. This group determines whether coding requests warrant a change to the national codes.

20. The HCPCS codes classify similar products that are medical in nature into categories to promote efficient claims processing.

21. Descriptions for each alpha-numeric HCPCS code identify a category of like items. Providers then use HCPCS codes to identify items on claim forms that are being billed to a private or public health insurer. *See, e.g.*, *UnitedHealthcare (UHC) Out of Network Claim Submission Instructions For Medical and Mental Health Claims*, UnitedHealthcare, at 2, https://bit.ly/3JWYzMK (referencing the use of current CPT and HCPCS codes); *Claims Processing Edits*, Humana, https://huma.na/37W5vwm (referencing same); *Provider Manual*, Aetna, at 64, https://aet.na/3uTYuW4 (referencing same).

II. HCPCS CODES ARE NOT USED TO MAKE DETERMINATIONS ABOUT COVERAGE.

22. "HCPCS is a system for identifying items and certain services." *Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures*, at 2. "It is not a

methodology or system for making coverage or payment determinations." *Id.* As a result, "[t]he existence of a code does not, of itself, determine coverage or non-coverage for an item or service." *Id.*

23. HCPCS codes are used for billing purposes, but "decisions regarding the addition, deletion, or revision of HCPCS codes are made independent of the process for making determinations regarding coverage and payment." *Id.*

24. As the American College of Obstetrics and Gynecology ("ACOG") has explained:

> The coding system is not a methodology for making coverage or payment determinations. Each payer makes determinations on coverage and payment outside this coding process. The descriptors of the codes identify a category of like items or services and typically do not identify specific products or brand or trade names.

New HCPCS Codes Established for Coding the Levonorgestrel-Releasing Intrauterine Contraceptive System 52-mg Intrauterine Device (IUD), Am. Coll. of Obstetricians & Gynecologists, https://bit.ly/3jN6aCT.

25. For example, with Medicare, regional Medicare Administrative Contractors ("MACs") make coverage determinations. Moreover, section 20.1.2 of Chapter 17 of the Medicare Claims Processing Manual makes clear that "[t]he absence or presence of a HCPCS code and its associated payment limit does not indicate Medicare coverage of the drug or biological." *Medicare Claims Processing Manual Chapter 17 – Drugs and Biologicals*, Ctrs. for Medicare and Medicaid Servs., https://go.cms.gov/3uRuTfF.

26. Further, private payors develop their own coverage policies independent of CMS coverage determinations. Some private payors currently have coverage policies for Lanreotide that allow for coverage of Lanreotide Acetate and recommend utilizing J1930 as the billing

code. *See* Cigna, Drug and Biologic Coverage Policy: Lanreotide for Non-Oncology Uses, https://bit.ly/3OhdHrN.

III. MISCELLANEOUS CODES *MAY* BE USED WHEN THERE IS NO EXISTING NATIONAL CODE THAT ADEQUATELY DESCRIBES THE BILLED ITEM.

27. The HCPCS Level II Code Set, like other national codes, includes "miscellaneous/not otherwise classified" codes. *Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures*, at 3. Providers *may* use miscellaneous codes when "there is no existing national code that adequately describes the item or service billed." *Id.* But providers are not required to use the miscellaneous codes if they believe that a drug product or other item/service is adequately described by an existing code.

28. To the extent no existing code describes a new product, and a manufacturer believes that a new code is needed, the manufacturer may submit a coding request to modify the HCPCS Level II Code Set. *See id.* at 4; *see also HCPCS Decision Tree*, Ctrs. for Medicare and Medicaid Servs., https://go.cms.gov/3KXlk4G (describing CMS's decision-making process to adjudicate requests to add or revise codes). If a company has an objection to a use code designation, it may present its objections to CMS.

IV. CMS DOES NOT ESTABLISH NEW OR MODIFIED HCPCS CODES UNLESS THERE IS NO EXISTING CODE THAT ADEQUATELY DESCRIBES THE NEW ITEM TO BE CODED.

29. Section 731 of the Medicare Modernization Act "does not require that a new code category or a product specific code be created for an item simply because a new coverage determination was made, without regard to codes available in the existing code set." *Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures*, at 5.

30. To the contrary, CMS applies the following criteria, among others, to determine whether there is "a demonstrated need for a new or modified code":

a. "When an existing code adequately describes the item in a coding request, no new or modified code is established. An existing code adequately describes an item in a coding request when the existing code describes items with the following":

i. "Functions similar to the item in the coding request"; and

ii. "No significant therapeutic distinctions from the item in the coding request."

b. "When an existing code describes items that provide almost the same functionality with only minor distinctions from the item in the coding request, the item in the coding request may be grouped with that code and the code descriptor modified to reflect the distinctions." *Id.*

31. CMS, in the proposed 2021 Physician Fee Schedule, explains that it determines the assignment of HCPCS codes to new drugs approved under the Section 505(b)(2) pathway on a "case by case basis," considering a product's active ingredient, drug name and description, a product's labeling, how the product is ordered/prescribed, and how the product is used clinically.

32. A determination by CMS that products should share the same use code for purposes of billing is not dependent on whether the FDA has concluded that the products are therapeutically equivalent. Indeed, there have been several instances in which CMS determined that drugs should share the same HCPCS code despite the absence of a therapeutical-equivalence determination by the FDA:

a. Before January 1, 2016, CMS assigned both Mirena (NDC 50419-423-01) and Liletta (NDC 52544-035-54) to HCPCS code J7302, even though Mirena and Liletta are not therapeutically equivalent.

b. CMS has assigned both Veletri (NDC 66215-0403-01) and Flolan (NDC 00173-0519-00) to HCPCS code J1325, even though Veletri and Flolan are not therapeutically equivalent.

c. In 2018, CMS assigned Prograf Suspension (NDCs 0469-1330-50 and 0469-1230-50) to HCPCS Code J7507, even though Prograf Suspension was not therapeutically equivalent to the brand and generic products already assigned to the code.

FACTUAL BACKGROUND

I. IPSEN DOMINATES THE LANREOTIDE ACETATE MARKET FOR 15 YEARS.

33. On or about January 15, 2007, the FDA accepted for filing Ipsen's New Drug Application ("NDA") for Somatuline® Depot, also known as Somatuline Autogel.

34. On or about August 31, 2007, the FDA granted Somatuline® Depot marketing approval in the United States for the treatment of Acromegaly.

35. On or about December 16, 2014, the FDA approved Somatuline® Depot for an additional indication: the treatment of Gastroenteropancreatic Neuroendocrine Tumors.

36. CMS assigned Somatuline® Depot HCPCS Code J1930.

37. Between approximately August 31, 2007 and December 16, 2021, Somatuline® Depot was the only FDA-approved Lanreotide Acetate injection for Acromegaly and Gastroenteropancreatic Neuroendocrine Tumors.

38. Somatuline® Depot had sales in the United States of approximately $867M for the 12-month period ending in October 2021.

II. THE APPROVAL OF CIPLA'S LANREOTIDE ACETATE PRODUCT THREATENS SOMATULINE® DEPOT AND, BY EXTENSION, IPSEN.

39. On Friday, December 17, 2021, the FDA approved Cipla's Lanreotide Acetate Product under an NDA (held by Cipla's affiliate, InvaGen) for the treatment of Acromegaly and Gastroenteropancreatic Neuroendocrine Tumors in the United States. The Lanreotide Acetate Product was approved under the Section 505(b)(2) pathway.

40. On Sunday, December 19, 2021, Cipla announced the FDA's approval of Cipla's Lanreotide Acetate Product. In its press release, Cipla noted that the "active ingredient, route of administration and strengths are the same as SOMATULINE DEPOT®, from Ipsen Biopharmaceuticals Inc." The press release made no representations regarding whether Cipla's Lanreotide Acetate Product and Somatuline® Depot are therapeutically equivalent.

41. According to Reuters, on Monday, December 20, 2021, Ipsen's share price dropped over 7%, placing Ipsen "among the five biggest fallers on pan-European STOXX 600 index." *See supra* ¶ 4, Vardon & Miridzhanian, *BUZZ-Ipsen drops after FDA approves competitor's generic drug*.

42. Analysts at JP Morgan predicted that competition from Cipla's Lanreotide Acetate Product could result in a 20% decline in U.S. sales of Somatuline® Depot in 2022, which, if accurate, would amount to a decrease of approximately $173.4M in annual revenue. *Compare id.*, *with supra* ¶ 1, Dutta, *Cipla gains 3% on USFDA nod to market Lanreotide*.

43. Cipla launched its Lanreotide Acetate Product on or around February 10, 2022.

III. IPSEN MAKES FALSE AND MISLEADING STATEMENTS ABOUT CIPLA'S LANREOTIDE ACETATE PRODUCT.

44. On or about February 7, 2022, Ipsen sent a letter to Cipla referencing a confidential communication between Cipla and one of Cipla's customers and threatening to pursue legal action (including punitive damages). In the letter, Ipsen accused Cipla (without evidence) of representing to customers that Cipla's Lanreotide Acetate Product (a) was "therapeutically equivalent" to Somatuline® Depot and (b) had been assigned to HCPCS code J1930, the code for Lanreotide used for Somatuline® Depot.

45. On or about February 10, 2022, Cipla responded to Ipsen. Cipla explained that it had never asserted in any public communication or in any communication with customers that

Cipla's Lanreotide Acetate Product was a "generic" version of Somatuline® Depot or "therapeutically equivalent" to Somatuline® Depot. As to Ipsen's objection regarding the J1930 code, Cipla explained that providers make their own decisions as to which HCPCS code to use for reimbursement.

46. On or about February 24, 2022, Ipsen informed Cipla that it had contacted CMS and intended, among other things, to ensure that the Medicare program rejects all reimbursement claims for Cipla's Lanreotide Acetate Product, except for claims submitted using the miscellaneous HCPCS code, J3490. Ipsen has no legitimate basis to interfere with the reimbursement of Cipla's Lanreotide Acetate Product, as it seeks to inject itself into a regulatory-review process in order to damage its direct competitor.

47. Not content merely to try to influence the regulatory process regarding HCPCS code usage, Ipsen took matters into its own hands, using its dominant market position to interfere with Cipla's current and prospective customer relationships by making false and/or misleading statements regarding Cipla and Cipla's Lanreotide Acetate Product. In particular, following Cipla's launch and beginning on or before February 24, 2022, Ipsen distributed a "Notice Regarding Somatuline® Depot and Cipla's Lanreotide Acetate Product" to providers and wholesale distributors in the marketplace for purchasing Lanreotide Acetate products. For the reasons described below, Ipsen's widely disseminated "notice" made several false and/or misleading statements, including:

a. Because Somatuline® Depot and Cipla's Lanreotide Acetate Product are separate single source drugs, the products must have independent HCPCS codes. This statement is false. CMS has exclusive authority to assign HCPCS codes and has not yet done so for Cipla's

Lanreotide Acetate Product. CMS has the authority to determine that the existing J1930 use code is appropriate for Cipla's Lanreotide Acetate Product.

b. J3490 (the code for miscellaneous drugs) must be used for Cipla's Lanreotide Acetate Product until CMS assigns it a unique code. There is no legal support for this instruction. To the contrary, CMS's May 18, 2007 guidance indicates that CMS has flexibility to assign a unique code, an existing code, or the miscellaneous code to a newly approved product like Cipla's Lanreotide Acetate Product.

c. Use of J1930 for Cipla's product may lead to payment delays, reversals, and denials. This statement misleadingly implies that Cipla's Lanreotide Acetate Product may not be covered by Medicare or private, commercial insurance if providers use HCPCS code J1930. That is wrong: Medicare Part B covers Cipla's Lanreotide Acetate Product regardless of the use code because Cipla's Lanreotide Acetate Product is a physician administered injectable furnished "incident to" physician's services. Likewise, Cipla's Lanreotide Acetate Product would be covered by a private, commercial insurance if the drug is covered under the health plan's policy. HCPCS codes do not govern coverage determinations either for Medicare or for private insurers.

d. Cipla's Lanreotide Acetate Product is not reimbursable under HCPCS billing and payment code J1930. This statement is false and/or misleading, as the statement wrongly suggests that HCPCS codes affect coverage determinations. In the case of Medicare, MACs make the determinations regarding coverage and the appropriate reimbursement. Cipla's Lanreotide Acetate Product is covered under Medicare Part B because it meets the definition of a Medicare Part B drug given that it is furnished "incident to" a physician's services. Commercial insurers likewise make coverage determinations, which do not depend on the code used, but rather on whether the drug is covered by the given commercial health plan. In addition, the statement also wrongly

suggests CMS has made a determination that payment code J1930 cannot be used for Cipla's Lanreotide Acetate Product, which is false for the reasons described above.

48. In or around February 2022, Ipsen also told providers and wholesale distributors that Cipla had falsely claimed that Cipla's Lanreotide Acetate Product was "therapeutically equivalent" to Somatuline® Depot. This statement is false and wrongfully disparages Cipla, as it falsely asserts that Cipla had lied to its customers about its own product. But Cipla has never made the claim of therapeutic equivalence attributed to it by Ipsen, either in its press release announcing the approval of its Lanreotide Acetate Product or otherwise. Cipla has also repeatedly explained to Ipsen that Cipla has never claimed that the products are therapeutically equivalent, but Cipla has persisted in making this untrue accusation. Upon information and belief, Ipsen never corrected its misrepresentation to Cipla customers.

49. Ipsen's false and/or misleading statements have created significant market confusion regarding coverage and reimbursement for Cipla's Lanreotide Acetate Product while also damaging Cipla's reputation. As a direct result of the false and/or misleading statements, the demand for Cipla's Lanreotide Acetate Product has been substantially depressed, resulting in decreased sales, revenue, and market share.

50. Faced with the uncertainty created by Ipsen's notice with the false and/or misleading statements in Paragraph 48, one of Cipla's largest wholesale customers contacted Cipla about the notice. The wholesaler apprised Cipla that demand for Cipla's Lanreotide Acetate Product had dropped off, and it attributed the decline in sales to Ipsen's notice.

51. Upon launch of its Lanreotide Acetate Product in February 2022, Cipla recorded robust initial sales, which is consistent with Cipla's projections regarding the market opportunity. But following Ipsen's efforts to create confusion about coverage and reimbursement for Cipla's

Lanreotide Acetate Product, and to damage Cipla's reputation with customers, Cipla's sales have eroded significantly. Based on its general experience and specific knowledge of the Lanreotide Acetate market, Cipla expected its weekly sales numbers *to increase* after a successful launch; instead, its sales have *decreased* substantially, with a more than 80% drop in weekly sales from mid-February 2022 to early April 2022.

52. Cipla has also been damaged by Ipsen's conduct in the form of strained business relationships, reputational harm, and lost goodwill, leading customers (providers and wholesale distributors) to purchase Somatuline® Depot instead of Cipla's Lanreotide Acetate Product.

IV. IPSEN'S FALSE AND MISLEADING STATEMENTS ARE PART OF A BROADER CAMPAIGN BY IPSEN TO IMPAIR COMPETITION.

53. Even before Cipla had launched it Lanreotide Acetate Product, Ipsen was doing all it could to prevent competition against Somatuline® Depot. On August 31, 2020, Ipsen filed a complaint against the U.S. Department of Health and Human Services (HHS) challenging the FDA's decision to continue regulating Somatuline® Depot as a drug product under the Food, Drug, and Cosmetic Act, 21 U.S.C. § 355, rather than as biological product under the Public Health Service Act, 42 U.S.C. § 262. Ipsen's avowed purpose in filing the suit was to deter competition by other companies seeking to market Lanreotide Acetate products. *See Ipsen Biopharmaceuticals, Inc. v. Becerra et al.*, C.A. No. 20-2437, 2021 WL 4399531, at *4 (D.D.C. Sept. 24, 2021) ("[Ipsen] alleges that the regulation of Somatuline Depot as a drug rather than as a biologic product exposes it to a greater risk of competition."). On September 24, 2021, the U.S. District Court for the District of Columbia dismissed Ipsen's challenge for lack of subject-matter jurisdiction. *See id.* at *10.

54. On March 30, 2022, following the FDA's approval of Cipla's Lanreotide Acetate Product, Ipsen filed a new complaint against HHS reprising its challenge to the FDA's decision to

continue regulating Somatuline® Depot as a biological product. This second complaint against HHS involved substantially the same issues that were raised in its prior lawsuit and which had been rejected both by the U.S. District Court for the District of Columbia and the FDA. *See Ipsen Biopharmaceuticals, Inc. v. Becerra et al.*, C.A. No. 22-860 (D.D.C.). In the suit, Ipsen alleges that if the FDA had transitioned Somatuline® Depot to regulation as a biological product, then approval of Cipla's Lanreotide Acetate Product would have been blocked. Ipsen further alleges that it has been harmed by competition from Cipla, which sells its Lanreotide Acetate Product for materially lower prices than Ipsen. *See id.*, Doc. 1 ¶ 97. Ultimately, Ipsen seeks an order that would require the FDA to withdraw its approval for Cipla's Lanreotide Acetate Product, thus restoring Ipsen's monopoly.

55. Ipsen has also used its complaint in that litigation against HHS to repeat several of its false and/or misleading statements regarding Cipla and Cipla's Lanreotide Acetate Product. In particular, Ipsen falsely alleges that Cipla (through an affiliate) "has been … referring to [its product] publicly as a 'generic.'" *Id.* ¶ 86. Ipsen also repeats its false assertion that "physicians and hospitals are *erroneously* billing [Cipla's Lanreotide Acetate Product] using HCPCS code J1930." *Id.* ¶ 91 (emphasis added).

56. Ipsen's attempt to use the regulatory process to block competition and its repetition of baseless accusations against Cipla in the action filed against HHS leave no doubt about the anticompetitive intent behind Ipsen's conduct. Ipsen has disseminated false and/or misleading statements about Cipla and Cipla's Lanreotide Acetate Product to wholesale distributors and healthcare providers in an effort to continue dominating a market it has had to itself for 15 years. As described above, Ipsen's unlawful, unfair, and anticompetitive conduct has injured and continues to injure Cipla.

CAUSES OF ACTION

I. UNFAIR COMPETITION – LANHAM ACT § 43(A), 15 U.S.C. § 1125(A)

57. Cipla incorporates by reference all of the paragraphs of this Complaint into this Count as if fully set forth herein.

58. Ipsen made false and misleading statements as to the reimbursability and coverage of Cipla's Lanreotide Acetate Product, including without limitation:

a. Because Somatuline® Depot and Cipla's Lanreotide Acetate Product are separate single source drugs, the products must have independent HCPCS codes;

b. J3490 (the code for miscellaneous drugs) must be used for Cipla's Lanreotide Acetate Product until CMS assigns it a unique code;

c. Use of J1930 for Cipla's Lanreotide Acetate Product may lead to payment delays, reversals, and denials; and

d. Cipla's Lanreotide Acetate Product is not reimbursable under HCPCS billing and payment code J1930.

59. The false and/or misleading statements in Paragraph 58 amount to actual deception or have at least a tendency to deceive a substantial portion of the intended audience as follows:

a. CMS has exclusive authority to assign HCPCS codes and it has made no decision regarding the code for Cipla's Lanreotide Acetate Product. Therefore, providers have discretion to bill Cipla's Lanreotide Acetate Product under J1930;

b. There is no legal support for Ipsen's statement that J3490 (the code for miscellaneous drugs) "must" be used for Cipla's Lanreotide Acetate Product until CMS assigns it a unique code;

c. HCPCS codes do not have any relationship to delays, reversals, or denials of payments. Providers' use of J1930 for Cipla's Lanreotide Acetate Product merely serves to identify the type of drug administered; it is not used to determine coverage; and

d. The presence or absence of a particular HCPCS code and its associated payment limit does not indicate coverage, *i.e.*, the reimbursability, of the drug. Rather, it is up to the regional MACs, among others, to make coverage determinations, which are independent from the HCPCS code use.

60. The false and/or misleading statements in Paragraph 58 are material in that they are likely to influence purchasing decisions by providers and wholesale distributors in the following ways:

a. Providers are less likely to demand Cipla's product because Ipsen's statements suggest that Cipla's Lanreotide Acetate Product is not reimbursable, *i.e.*, that is not covered under Medicare or by private commercial insurance. In fact, Medicare covers Cipla's Lanreotide Acetate Product because Cipla's Lanreotide Acetate Product is a physician administered injectable furnished "incident to" physician's services. Likewise, Cipla's Lanreotide Acetate Product would be covered by a private, commercial insurer if the drug is covered under the health plan's policy. HCPCS codes do not govern coverage for either Medicare or private insurers.

b. Wholesale distributors are less likely to demand Cipla's product because they are concerned about potential issues with coverage arising from Ipsen's misrepresentations regarding the propriety of using the J1930 code for Cipla's product. In fact, following Ipsen's false and/or misleading statements in Paragraph 58, demand for Cipla's product dropped substantially. A leading wholesaler attributed a decline in demand among downstream purchasers for Cipla's

Lanreotide Acetate Product to the notice disseminated by Ipsen with the false and/or misleading statements in Paragraph 58.

61. Ipsen also made false and/or misleading statements when it told customers for Lanreotide Acetate that Cipla incorrectly represented that its product was therapeutically equivalent to Somatuline® Depot.

62. The false and misleading statement in Paragraph 61 amounts to actual deception or has at least a tendency to deceive a substantial portion of the intended audience because Cipla has never represented that Cipla's Lanreotide Acetate Product was therapeutically equivalent to Somatuline® Depot.

63. The false and/or misleading statement in Paragraph 61 is material in that it is likely to influence purchasing decisions by providers and wholesale distributors because both providers and wholesale distributors are less likely to demand Cipla's Lanreotide Acetate Product as they have been wrongly led to question Cipla's honesty and integrity in light of Ipsen's false claim that Cipla is misrepresenting the nature of its own product.

64. Cipla's Lanreotide Acetate Product has travelled in interstate commerce, as it has been purchased by wholesale distributors and providers in multiple states.

65. Ipsen's false and/or misleading statements in Paragraphs 58 and 61 constitute "commercial advertising or promotion" under 15 U.S.C. § 1125(a)(1)(B) as follows:

a. They are commercial speech by Ipsen;

b. Ipsen is in commercial competition with Cipla for the Lanreotide Acetate market;

c. Upon information and belief, Ipsen made its statements for the purpose of influencing customers (providers and wholesale distributors) to buy Somatuline® Depot, as Ipsen

made these statements shortly after Cipla's product launch in a transparent effort to maintain Ipsen's market dominance for its most important product; and

d. Ipsen's statements have been disseminated sufficiently to the relevant purchasing public, namely, a variety of providers and wholesale distributors who are Cipla's customers for Lanreotide Acetate products. Cipla became aware of the widespread dissemination of Ipsen's statements when a wholesaler, in response to the marketplace confusion that Ipsen created, brought the communication to Cipla's attention and informed Cipla that the communication had been distributed by Ipsen to customers.

66. The false and/or misleading statements in Paragraphs 58 and 61 have injured and are likely to further injure Cipla because Ipsen has generated confusion about whether Cipla's Lanreotide Acetate Product will be covered and reimbursed and falsely maligned Cipla's trustworthiness and credibility, depressing provider and wholesale distributor demand for Cipla's Lanreotide Acetate Product and leading to declining sales of Cipla's Lanreotide Acetate Product. The statements have also harmed and continue to harm Cipla's business relationships and goodwill with providers and wholesale distributors, who are Cipla's customers.

67. For these reasons, Cipla is entitled to recover the damages sustained by Cipla in an amount to be determined at trial, which damages may be increased by up to three times by the court according to the circumstances of the case, disgorged profits from Ipsen, and/or the costs of the action, pursuant to 15 U.S.C. § 1117(a).

68. Unless permanently enjoined by the Court, Ipsen's actions will continue to cause irreparable harm to Cipla for which there is no adequate remedy at law and, as a result, Cipla is entitled to permanent injunctive relief pursuant to 15 U.S.C. § 1116(a).

II. DECEPTIVE TRADE PRACTICES – DELAWARE UNIFORM DECEPTIVE TRADE PRACTICES ACT, 6 *DEL. C.* § 2532

69. Cipla incorporates by reference all of the paragraphs of this Complaint into this Count as if fully set forth herein.

70. Ipsen has engaged in deceptive trade practices by making false and/or misleading representations as to the reimbursability and coverage of Cipla's Lanreotide Acetate Product, including without limitation that:

a. Because Somatuline® Depot and Cipla's Lanreotide Acetate Product are separate single source drugs, the products must have independent HCPCS codes;

b. J3490 (the code for miscellaneous drugs) must be used for Cipla's Lanreotide Acetate Product until CMS assigns it a unique code;

c. Use of J1930 for Cipla's Lanreotide Acetate Product may lead to payment delays, reversals, and denials; and

d. Cipla's Lanreotide Acetate Product is not reimbursable under HCPCS billing and payment code J1930.

71. Ipsen also made false and/or misleading statements when it told customers for Lanreotide Acetate that Cipla incorrectly represented that its product was therapeutically equivalent to Somatuline® Depot.

72. These statements are false and misleading for the reasons described above, including in Paragraphs 59-60, 62-63.

73. Ipsen's actions and misrepresentations, individually or taken together, are likely to cause confusion, deception, or misunderstanding and constitute violations of, *inter alia*, 6 *Del. C.* § 2532(a)(5), (a)(7), (a)(8), and (a)(12).

74. Ipsen's deceptive trade practices have confused and deceived, and will continue to confuse and deceive, Cipla's customers and potential customers of its Lanreotide Acetate Products because Ipsen has generated confusion about whether Cipla's Lanreotide Acetate Product will be covered and reimbursed by governmental and commercial payors, and falsely maligned Cipla's trustworthiness and credibility. Ipsen's conduct has depressed provider and wholesale distributor demand for Cipla's Lanreotide Acetate Product, leading to declining sales of Cipla's Lanreotide Acetate Product. Ipsen's conduct has also harmed and continues to harm Cipla's business relationships and goodwill with providers and wholesale distributors, who are Cipla's customers.

75. Ipsen's deceptive trade practices have been deliberate and willful.

76. For the reasons set forth in Count I, Cipla is entitled to recover the damages sustained by Cipla in an amount to be determined at trial, which damages may be trebled pursuant to 6 *Del. C.* § 2533.

77. Unless permanently enjoined by the Court, Ipsen's actions will continue to cause irreparable harm to Cipla for which there is no adequate remedy at law and, as a result, Cipla is entitled to permanent injunctive relief pursuant to 6 *Del. C.* § 2533.

III. UNFAIR COMPETITION – DELAWARE COMMON LAW

78. Cipla incorporates by reference all of the paragraphs of this Complaint into this Count as if fully set forth herein.

79. Prior to Ipsen's actions, Cipla had a reasonable expectancy of entering into valid business relationships with wholesale distributors and providers of Cipla's Lanreotide Acetate Product with whom Cipla has existing relationships.

80. Ipsen wrongfully interfered with Cipla's business relationships by engaging in unfair and deceptive conduct to interfere with Cipla's customer relations, including by disseminating the false and/or misleading statements described in Paragraphs 58 and 61 above.

81. As a result of Ipsen's wrongful and intentional actions, Cipla's reasonable expectations of relationships with existing and/or prospective customers have been damaged, as illustrated by the significant drop in sales of Cipla's Lanreotide Acetate Product that directly followed Ipsen's dissemination of false and/or misleading statements. Ipsen has generated confusion about whether Cipla's Lanreotide Acetate Product will be covered and reimbursed and falsely maligned Cipla's trustworthiness. Ipsen's conduct has depressed provider and wholesale distributor demand for Cipla's Lanreotide Acetate Product, leading to declining sales of Cipla's Lanreotide Acetate Product, decreased revenue, and decreased market share. The statements have also harmed and continue to harm Cipla's business relationships and goodwill with providers and wholesale distributors, who are Cipla's customers.

82. For the reasons set forth in Count I, Cipla is entitled to recover the damages sustained by Cipla in an amount to be determined at trial.

83. Unless permanently enjoined by the Court, Ipsen's actions will continue to cause irreparable harm to Cipla for which there is no adequate remedy at law and, as a result, Cipla is entitled to permanent injunctive relief.

IV. TORTIOUS INTERFERENCE WITH ECONOMIC ADVANTAGE

84. Cipla incorporates by reference all of the paragraphs of this Complaint into this Count as if fully set forth herein.

85. Cipla had a reasonable expectation of economic advantage, namely, substantial sales to wholesale distributors and providers of Cipla's Lanreotide Acetate Product with whom Cipla has existing relationships, and who purchased Cipla's Lanreotide Acetate Product when it was first offered in February 2022.

86. Cipla lost substantial sales of its Lanreotide Acetate Product as a direct result of Ipsen's malicious interference. Specifically, Ipsen made the false and/or misleading statements as

alleged above, which resulted in the deception of Cipla's customers, in the manner specified above. Ipsen's false and/or misleading statements to Cipla customers influenced purchasing decisions and depressed provider and wholesale distributor demand for Cipla's Lanreotide Acetate Product, leading to declining sales of Cipla's Lanreotide Acetate Product and decreased revenue and market share. The statements have also harmed and continue to harm Cipla's business relationships and goodwill with providers and wholesale distributors, who are Cipla's customers.

87. Ipsen's false and/or misleading statements were malicious:

a. Ipsen is a billion-dollar biopharmaceutical company;

b. For over fifteen years, Ipsen has held an unchecked position as the sole FDA-approved Lanreotide Acetate injection;

c. Within one business day of the FDA's approval of Cipla's Lanreotide Acetate Product, Ipsen's stock price started falling and analysts predicted that Ipsen would lose hundreds of millions of dollars in annual revenue from competition by Cipla;

d. Ipsen had no justification for making false and/or misleading statements about the proper HCPCS coding for Cipla's Lanreotide Acetate Product or the coverage of that product. To the extent Ipsen had any legitimate concerns about coding practices, Ipsen knew or should have known to raise those concerns directly with CMS rather than with providers and wholesale distributors (who are Cipla's customers);

e. Instead of raising any concerns solely with CMS, Ipsen disparaged Cipla and Cipla's Lanreotide Acetate Product by widely disseminating false and/or misleading statements to providers and wholesale distributors (who are Cipla's customers);

f. In making these false and/or misleading statements to Cipla's customers, Ipsen knew or should have known both that HCPCS codes are unrelated to determinations of coverage

and that CMS has not yet made a determination regarding the appropriate use code for the Lanreotide Acetate Product;

g. Ipsen had no good faith basis for claiming that Cipla incorrectly represented that Cipla's Lanreotide Acetate Product was therapeutically equivalent to Somatuline® Depot since Cipla's press release did not make this claim, Cipla told Ipsen that it never made this claim, and Cipla has, in fact, never made this claim; and

88. Cipla suffered substantial losses as a direct result of Ipsen's wrongful interference, including lost profits, because depressed provider and wholesale distributor demand resulted in fewer purchases of Cipla's Lanreotide Acetate Product. The statements have also harmed and continue to harm Cipla's business relationships and goodwill with providers and wholesale distributors, who are Cipla's customers.

89. Because Ipsen's actions caused Cipla's losses, Cipla is entitled to recover the damages sustained by Cipla in an amount to be determined at trial, including Cipla's lost profits or disgorgement of Ipsen's profits.

90. Unless permanently enjoined by the Court, Ipsen's actions will continue to cause irreparable harm to Cipla for which there is no adequate remedy at law and, as a result, Cipla is entitled to permanent injunctive relief.

V. TRADE LIBEL

91. Cipla incorporates by reference all of the paragraphs of this Complaint into this Count as if fully set forth herein.

92. Ipsen made false and/or misleading statements about Cipla's business, described above, that disparaged Cipla's business and Lanreotide Acetate Product and created consumer confusion or misunderstanding and/or deceived or misled consumers regarding Cipla's products and business as described above.

93. Ipsen's false and/or misleading statements were intended to prevent or otherwise interfere with Cipla's relationships with others, namely, providers and wholesaler distributors. Ipsen made the false and/or misleading statements above in order to deceive Cipla's customers, in the manner specified above, and thereby influence purchasing decisions and depress demand for Cipla's Lanreotide Acetate Product. The result of Ipsen's false and/or misleading statements is fewer purchases of Cipla's Lanreotide Acetate Product than would have occurred but-for Ipsen's disparagement and substantially decreased sales, revenue, and market share for Cipla.

94. Ipsen's false and/or misleading statements were made to third persons (providers and wholesale distributors), including existing and prospective customers of Cipla, and played a material part in inducing those providers and wholesale distributors to reduce their dealings with Cipla, as described above.

95. Ipsen either knew that its statements were false and/or misleading or acted in reckless disregard of their truth or falsity, as the following demonstrates:

a. Ipsen is a billion-dollar biopharmaceutical company;

b. To the extent Ipsen had legitimate concerns about coding practices, it could and should have raised those concerns with CMS, as Ipsen either knows or should have known;

c. In making these false and/or misleading statements to Cipla's customers, Ipsen knew or should have known that HCPCS codes are unrelated to determinations of coverage and that CMS has not yet made a determination regarding the appropriate use code for the Lanreotide Acetate Product; and

d. Ipsen had no good faith basis for claiming that Cipla incorrectly represented that Cipla's Lanreotide Acetate Product was therapeutically equivalent to Somatuline® Depot since

Cipla's press release did not make this claim, Cipla told Ipsen that it never made this claim, and Cipla never, in fact, made this claim.

96. Ipsen either knew or intended that its false and misleading statements would cause pecuniary loss and/or reasonably should have known that pecuniary loss would result from its false and misleading statements.

97. As a direct and proximate result of Ipsen's actions, Cipla has suffered and will continue to suffer harm, including in the form of lost profits and lost goodwill

98. Because Ipsen's actions caused Cipla's losses, Cipla is entitled to recover the damages sustained by Cipla in an amount to be determined at trial, in addition to costs and fees as allowed by law.

99. Unless permanently enjoined by the Court, Ipsen's actions will continue to cause irreparable harm to Cipla for which there is no adequate remedy at law and, as a result, Cipla is entitled to permanent injunctive relief.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Cipla demands a jury trial on all issues that are triable by a jury in this action.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in favor of Plaintiff and against Defendant, as follows:

A. A JUDGMENT awarding Plaintiff compensatory and consequential damages, in an amount to be proven at trial, trebled, in the Court's discretion, and which may include Defendant's profits, in an amount to be proven at trial, and the costs of the action;

B. An ORDER permanently enjoining Defendant from making any representations

pertaining to the appropriate HCPCS code for Cipla's Lanreotide Acetate Product, excepting communications with CMS or any other government agency or contractor, unless and until CMS determines the appropriate HCPCS code for Cipla's Lanreotide Acetate Product;

C. Reasonable attorneys' fees and costs; and

D. Such other and further relief as the Court deems just and equitable.

Respectfully submitted,

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